Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JÜRG ZIMMERMANN,
BERTRAND SUTTER, and
HANS M. BÜRGER

Appeal No. 2003-0919
Application No. 09/463,097

ON BRIEF

WINTERS, SCHEINER, and MILLS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

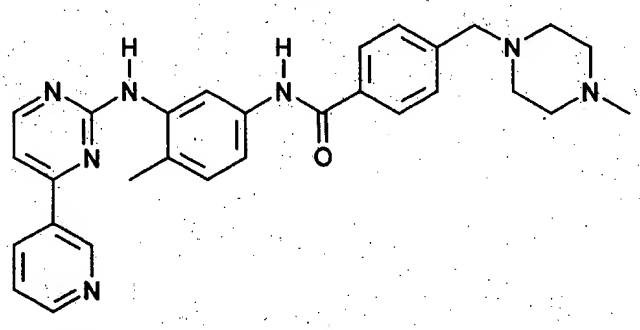
This appeal was taken from the examiner's decision rejecting claims 1 through 8, 10, and 13 through 16. Claim 12, which is the only other claim remaining in the application, stands allowed. (Examiner's Answer, Paper No. 17, section (3)).

The Invention

The invention relates to a particular, non-hygroscopic crystalline form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]-benzamide, said to have advantageous flow

properties. In their specification and claims, applicants describe this non-hygroscopic form as the β-crystal form of the above-mentioned compound. Claims 1, 4, 10, and 14, which are illustrative of the subject matter on appeal, read as follows:

1. A crystalline form of the monomethanesulfonic acid addition salt of a compound of formula I,



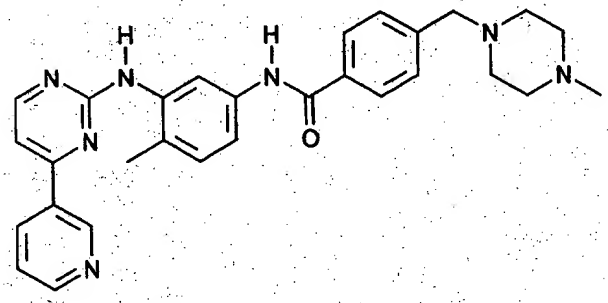
(I)

which is non-hygroscopic in a glass climatic chamber at 25 °C and relative humidities up to and including 93%.

4. A crystalline form according to claim 1 of the methanesulfonic acid addition salt of a compound of formula I, which comprises at least 99% by weight crystals of the β-modification and has a melting point below 225°C.

10. A pharmaceutical composition, comprising the β-crystal form according to claim 1 of the methanesulfonic acid addition salt of a compound of formula I and a pharmceutically acceptable carrier.

14. A method for treating a tumor disease in a patient, which comprises administering to the patient an effective amount of a compound of the formula



in its β-crystal modification.

For the sake of completeness, we note what appears to be an inadvertent error in claim 14. In that claim, applicants do not recite the β-crystal form of the methanesulfonic acid addition salt of the illustrated compound. Manifestly, the methanesulfonic acid addition salt is intended. (Appeal Brief, Paper No. 16, page 5, second full paragraph).

The Prior Art Reference

The prior art reference relied on by the examiner is:

Zimmermann	5,521,184	May 28, 1996

The Rejections

Claims 1, 4 through 8, 15, and 16 stand rejected under 35 U.S.C. § 112, second paragraph, as not particularly pointing out and distinctly claiming the subject matter which applicants regard as their invention. Claim 14 stands rejected under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure. Finally, claims 1 through 8, 10, and 13 through 16 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Zimmermann.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including Figures 1, 2, and 3, and all of the claims on appeal; (2) applicants' Appeal Brief (Paper No. 16) and the Reply Brief

(Paper No. 18); (3) the Examiner's Answer (Paper No. 17); and (4) the above-cited Zimmermann patent.

On consideration of the record, including the above-listed materials, we reverse each of the examiner's rejections.

Section 112

In our judgment, claims 1, 4 through 8, 15, and 16 set out and circumscribe a particular area with a reasonable degree of precision and particularity; and the examiner's rejection of these claims under 35 U.S.C. § 112, second paragraph, for indefiniteness, lacks merit. We shall not belabor the record with extensive commentary on this point, but simply refer to applicants' discussion in the Appeal Brief, page 4, with which we agree. Additionally, the examiner does not invite attention to any language or limitation in claims 1, 4 through 8, 15, or 16 which would give rise to a case of indefiniteness.

The rejection under 35 U.S.C. § 112, second paragraph, is reversed.

Respecting the rejection of claim 14 under 35 U.S.C. § 112, first paragraph, we again refer to applicants' discussion in the Appeal Brief (pages 5 and 6), with which we agree. We also find that the examiner, in setting forth this rejection, did not adequately take into account relative teachings in the prior art. In this regard, we here reproduce claims 21 and 22 of the Zimmerman patent:

> 21. A pharmaceutical composition for the treatment of tumours in warm-blooded animals including humans, comprising, in a dose effective against tumours, a compound of formula I according to claim 1, or a

> pharmaceutically acceptable salt of such a compound having at least one salt-forming group, together with a pharmaceutical carrier.
>
> 22. A method of treating warm-blooded animals including humans, which comprises administering to such a warm-blooded animal suffering from a tumoral disease a dose, effective against tumours, of a compound of formula I according to claim 1 or of a pharmaceutically acceptable salt of such a compound having at least one salt-forming group.

Under the provisions 35 U.S.C. § 282, a patent shall be presumed valid; and each claim of a patent shall be presumed valid independently of the validity of other claims. Accordingly, claims 21 and 22 of U.S. Patent No. 5,521,184 (the Zimmermann patent), shall be presumed valid. We may presume, therefore, that claims 21 and 22 are based on an enabling disclosure; and that the specification of the Zimmermann patent teaches any person skilled in the art how to use a compound of formula I, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. In claim 23, Zimmermann recites imatinib, a specific compound within the scope of formula I, or a pharmaceutically acceptable salt thereof. In light of 35 U.S.C. § 282, therefore, we may presume that the specification of the Zimmermann patent teaches any person skilled in the art how to use imatinib, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. On these facts, we disagree that the examiner has set forth adequate reasons or evidence to doubt the objective truth of statements in applicants' specification that an effective amount of the β-crystal form of

imatinib mesylate may be administered to a patient as the manipulative step in a method for treating tumour disease in a patient.

The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

Sections 102(b)/103(a)

For the purposes of this appeal, we shall assume arguendo, without deciding, that Zimmermann describes the methanesulfonic acid addition salt of imatinib within the meaning of 35 U.S.C. § 102(b). Nonetheless, we agree with applicants that Zimmermann contains insufficient disclosure to support a finding of anticipation of the appealed claims which recite a non-hygroscopic or β-crystalline form of the methanesulfonic acid addition salt of imatinib. In fact, with respect to the particular polymorphic form recited (non-hygroscopic or β-crystalline form), the examiner acknowledges that "Zimmermann is silent as to the existence of one or more forms for its salts." (Paper No. 17, page 7, lines 5 and 6).

The examiner would shift the burden of persuasion to applicants to establish that the β-crystalline form recited in their claims "cannot be made following routine conditions." (Paper No. 17, page 9, line 4). Stated another way, the examiner would place the burden on applicants to establish that the non-hygroscopic or β-crystalline form of the methanesulfonic acid addition salt of imatinib is not inherently produced using "routine procedures" disclosed by Zimmermann in column 19. (Paper No. 17, page 7, lines 4 through 9). This constitutes reversible error.

As stated in applicants' specification:

> It has now been surprisingly found that a crystal form may under certain conditions be found in the methanesulfonate salt of this compound [imatinib] which is described hereinafter as β-crystal form, and which has very advantageous properties. [Specification, page 1, third paragraph].

The examiner does not deny that applicants' specification teaches any person skilled in the art how to make the β-crystalline form of the methanesulfonic acid addition salt of imatinib. Nor can the examiner point to any passage in Zimmermann disclosing or suggesting applicants' method for making the β-crystalline form, or establishing a reasonable basis for concluding that the methanesulfonic acid addition salt of imatinib meets all limitations of the appealed claims. On the contrary, the examiner acknowledges that "Zimmermann is silent as to the existence of one or more forms for its salts;" and the examiner has withdrawn the previously entered rejection of process claim 12 (Paper No. 17, section (3)).

On these facts, the examiner is not in a position to invoke the principles enunciated in In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596-97 (CCPA 1980); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); and In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971). Rather, the facts here more closely resemble those presented to another merits panel of this board in Ex parte Skinner, 2 USPQ2d 1788 (Bd. Pat. App. & Int. 1986). As stated by the Board in Skinner:

> We are mindful that there is a line of cases represented by In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971) which indicates that where an examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject

> matter may, in fact, be an inherent characteristic of the prior art, the examiner possesses the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. Nevertheless, before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art. In the case before us, no such evidence or reasoning has been set forward. [Id. at 1789].

See Ex. Ans.

The rejection under 35 U:S.C. § 102(b) is reversed.

Respecting the rejection under 35 U.S.C. § 103(a), the examiner notes that Zimmermann's compounds can be used in the therapy of tumoral diseases. Again, we shall assume arguendo, without deciding, that Zimmermann describes the methanesulfonic acid addition salt of imatinib. The examiner apparently would invoke a per se rule of obviousness, viz., that merely changing the form, purity, or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable. See Ex parte Hartop, 139 USPQ 525 (Bd. App. 1962). The examiner argues that (1) the β-crystalline form of the methanesulfonic acid addition salt of imatinib is merely a different polymorphic form of Zimmermann's methanesulfonic acid addition salt of imatinib; (2) the β-crystalline form recited in applicants' claims and the compound described by Zimmermann both possess anti-tumoral activity; and (3) accordingly, the subject matter sought to be patented in the appealed claims would have been prima facie obvious in view of Zimmermann. We disagree.

First, as stated in In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995):

> The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention--including all its limitations--with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on per se rules of obviousness is legally incorrect and must cease.

Second, the principle of law enunciated in Ex parte Hartop, 139 USPQ 525 (Bd. App. 1962) has been substantially discredited in In re Cofer, 354 F.2d 664, 667-68, 148 USPQ 268, 270-71 (CCPA 1966).

Third, on this record, the examiner has not adequately explained how a person having ordinary skill would have been led from "here to there," i.e., from the methanesulfonic acid addition salt of imatinib to the non-hygroscopic or β-crystalline form of that compound recited in the appealed claims.

The rejection under 35 U.S.C. § 103(a) is reversed.

Conclusion

In conclusion, for the reasons set forth, we do not sustain the examiner's rejections 35 U.S.C. § 112, second paragraph; 35 U.S.C. § 112, first paragraph; 35 U.S.C. § 102(b); or 35 U.S.C. § 103(a).

The examiner's decision rejecting claims 1 through 8, 10, and 13 through 16 is reversed.

REVERSED

Sherman D. Winters)
Administrative Patent Judge)
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)
Toni R. Scheiner) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Demetra J. Mills) INTERFERENCES
Administrative Patent Judge)

Thomas Hoxie, Novartis
Novartis, Corporate Intellectual Property
One Health Plaza 430/2
East Hanover, NJ 07936-1080

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